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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/724,661	11/28/2000	Derek O'Hagan	1413.101	7716

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EXAMINER

STUCKER, JEFFREY J

ART UNIT	PAPER NUMBER
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1648

DATE MAILED: 11/13/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

Applicant(s)

Examiner

Group Art Unit

—The MAILING DATE of this communication appears on the cover sheet beneath the correspondence address—

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, such period shall, by default, expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).

Status

- ☒ Responsive to communication(s) filed on 7/24/02 & 10/22/02
- ☐ This action is **FINAL**.
- ☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

- ☒ Claim(s) 1-3, 5-7, 11, 14-19, 21, & 22 is/are pending in the application.
- Of the above claim(s) _____ is/are withdrawn from consideration.
- ☐ Claim(s) _____ is/are allowed.
- ☒ Claim(s) 1-3, 5-7, 11, 14-19, 21, & 22 is/are rejected.
- ☐ Claim(s) _____ is/are objected to.
- ☐ Claim(s) _____ are subject to restriction or election requirement.

Application Papers

- ☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.
- ☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.
- ☐ The drawing(s) filed on _____ is/are objected to by the Examiner.
- ☐ The specification is objected to by the Examiner.
- ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119 (a)-(d)

- ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
- ☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been received.
- ☐ received in Application No. (Series Code/Serial Number) _____.
- ☐ received in this national stage application from the International Bureau (PCT Rule 1.7.2(a)).

*Certified copies not received: _____

Attachment(s)

- ☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). _____ ☐ Interview Summary, PTO-413
- ☐ Notice of Reference(s) Cited, PTO-892 ☐ Notice of Informal Patent Application, PTO-152
- ☐ Notice of Draftsperson's Patent Drawing Review, PTO-948 ☐ Other _____

Office Action Summary

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed on 10/22/02 in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 7/24/02 has been entered. Claims 4, 9, 10, 12, and 13 are canceled. Claims 1-3, 5-7, 11, 14-19, 21, and 22 are pending and rejected.

Applicant's comments concerning the dependancy of claim 5 are noted. A review of the marked-up copy of the amendments to the claims in paper #8 shows that the dependency should be from claim 1 and will be treated as such.

Claim 22 is objected to for the misspelling of "microsphere".

The rejection of claims 1-4, 9, 11, 12, 14-19, 21 and 22 under 35 U.S.C. § 102(a) as being anticipated by Gombotz et al. (US 5,900,238) **is withdrawn** in view of applicant's amendment to the claims.

The rejection of claims 1-7, 9-19, 21, and 22 under 35 U.S.C. § 103(a) as obvious over Gombotz et al. (US 5,900,238) in view of both Partidos et al. (Immunology 1996) and Callegaro et al. (EP 0 517 565 A3) **is withdrawn** in view of applicant's amendment.

The following is a quotation of 35 U.S.C. § 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. § 103, the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 C.F.R. § 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of potential 35 U.S.C. § 102(f) or (g) prior art under 35 U.S.C. § 103(a).

Claims 1-3, 5-7, 11, 14-19, 21, and 22 are rejected under 35 U.S.C. § 103(a) as obvious over Callegaro et al. (EP 0 517 565 A3) in view of both Partidos et al. (Immunology 1996) and Koichiro (JPO 05163161, IDS ref. AO-1).

The instant invention directed to a composition that comprises hyaluronic acid ester polymer formed into microspheres and an antigen adsorbed on the microspheres. The instant invention further comprises an adjuvant which is further limited to being LT-K63 or LT-K72 and the antigen being a viral antigen, more specifically, influenza.

Callegaro et al. teach that hyaluronic acid is a known and widely used polymeric carrier for release systems for pharmacologically active molecules. See page 2, lines 41-54. They teach the addition of numerous types of proteins to the surface of hyaluronic acid ester microspheres. For instance, see example 2 (insulin), example 10 (NGF), and example 12 (CNTF), as well as others. Also, see the claims which state that the antigen can be surrounded by or adhered to the hyaluronic acid ester microspheres. The reference does not specifically teach the claimed antigen or the inclusion of LT-K63.

The reference does not discuss the specifically claimed adjuvants or using influenza. Partidos et al. teach LT-K63 as an effective mucosal adjuvant. It would have been obvious to one of ordinary skill in the art at the time the invention was made to use the specific adjuvant taught by Partidos et al. as the adjuvant to further enhance the drug delivery as taught by Callegaro et al.

Koichiro teaches an influenza vaccine comprising hyaluronic acid. The abstract does not teach the particular structure of the hyaluronic acid but does demonstrate that influenza antigen is compatible with hyaluronic acid compositions. One can rely on Callegaro for a teaching of how to make and use the hyaluronic acid microspheres. Therefore, the instant invention is as obvious over Callegaro et al. in view of both Partidos et al. and Koichiro.

No claims are allowed.

Papers related this application may be submitted to Group 1600 by facsimile transmission. Papers should be faxed to Group 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG (November 15, 1989).

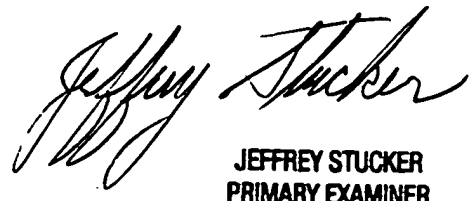
The Group 1600 Fax numbers are: (703) 308-4242 and (703) 305-3014.

Unofficial communications may be faxed to: (703) 308-4426.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jeffrey Stucker whose telephone number is (703) 308-4237. The examiner can normally be reached Monday to Thursday from 7:00am to 5:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Housel, can be reached on (703) 308-4027.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.



JEFFREY STUCKER
PRIMARY EXAMINER